

[Doc. No. 62]

THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

SHIRE LLC,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Consolidated
	:	Civil No. 14-5694 (RMB/JS)
COREPHARMA, LLC,	:	
	:	
Defendant.	:	
	:	
SHIRE LLC,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil No. 14-6095 (RMB/JS)
	:	
AMERIGEN PHARMACEUTICALS LTD,	:	
	:	
Defendant.	:	
	:	
SHIRE LLC,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil No. 15-1454 (RMB/JS)
	:	
PAR PHARMACEUTICAL, INC.,	:	
et al.,	:	
	:	
Defendants.	:	
	:	

MEMORANDUM OPINION AND ORDER

Background

This Memorandum Opinion and Order is a direct follow up to the Court's May 27, 2015 Memorandum and Order [Doc. No. 59]

addressing a dispute between Shire and Amerigen involving their Discovery Confidentiality Order ("DCO") in this patent infringement case. (Hereinafter referred to as the "Order"). Prior to entering the Order, Shire and Amerigen sought the Court's interpretation of paragraph 5.3 of New Jersey's standard DCO. The parties disputed whether under paragraph 5.3 Shire could use Amerigen's confidential information produced in discovery, specifically its Abbreviated New Drug Application ("ANDA"), to determine if Amerigen infringed U.S. Patent No. 6,913,768 ("the '768 Patent"), a Shire patent not named in the complaint. Amerigen sought to amend the DCO to clarify that confidential information exchanged during discovery may only be used with respect to the patents named in the complaint, U.S. Patent Nos. RE42,096 (the '096 Patent) and RE41,148 (the '148 Patent).<sup>1</sup> In other words, Amerigen wanted to bar Shire from reviewing its ANDA to determine if the '768 patent was infringed.

On May 27, 2015, the Court entered its Order denying without prejudice Amerigen's motion to amend the DCO. The Court determined that:

[A] party may use confidential information to add a new patent to a case, provided that the new patent is sufficiently related to the pleaded claims and defenses that an amendment would be permitted under

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<sup>1</sup> At the present time, this action addresses whether Amerigen's proposed generic version of Adderall XR® infringes certain claims within Shire's '096 and '148 Patents. For additional background, see the Court's May 27, 2015 Order.

the applicable Rules of Civil Procedure. As a result, Shire may only use Amerigen's confidential information to determine whether the '768 Patent should be added to the complaint if the '768 Patent is sufficiently related to the patents-in-suit so that an amendment would be permitted under Rule 15.

Order at 17. The Court's ruling derived from the fact that paragraph 3 of the DCO provides that confidential information may only be used for the prosecution or defense of "this action." The Court reasoned that "[t]he term limiting the use of confidential information 'to this action' is broader than Amerigen's proposal seeking to limit the use to only the 'claims and defenses' already asserted in the complaint." Id. at 7. The Court's ruling made it clear, however, that Shire's use of Amerigen's confidential information is not unlimited. Id. at 15. As noted, Shire may use Amerigen's confidential information to determine if a new patent may be added to the case only if the new patent is sufficiently related to the patents named in the complaint that joinder of the new patent would be permitted under Fed. R. Civ. P. 15. The difficulty the Court faces is that "there appears to be no clear-cut standard for determining whether patents are 'related'." Id. at 17. Further, as the Court previously noted, "[t]he precise standard the Court must use to determine if Shire's new patent ['768] is sufficiently related to the patents-in-suit is not consistently set forth in the case law." Id. at 15.

Through no fault of the parties, the Court noted in its Order that sufficient information was not provided for the Court to determine whether the '768 Patent was "sufficiently related" to the patents-in-suit. In response, the parties submitted supplemental letter briefs which are now before the Court. Not unexpectedly, Shire argues the '768 Patent is related to the patents in suit and Amerigen claims it is not related. For the reasons to be discussed, the Court finds the '768 Patent is sufficiently related to the patents-in-suit so that an amendment would be permitted under Rule 15.<sup>2</sup> Thus, Shire may review Amerigen's confidential information, including its ANDA, to determine if the '768 Patent was infringed.

In its letter brief Shire argues that the '768 Patent is sufficiently related to the '096 and '148 Patents-in-suit for three (3) reasons: (1) the claims and specification of the '768 Patent refer extensively to Adderall XR®; (2) all three patents relate to components of pharmaceutical formulations suitable for oral administration and delivery of amphetamine salts; and (3) the three listed inventors of the '768 Patent are also listed inventors for

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<sup>2</sup> As the Court stated in its May 27, 2015 Order, the Court's analysis focuses on whether the '768 Patent is sufficiently related to the patents-in-suit to permit joinder under Rule 15. In this context the Court does not need to address undue delay, futility, etc., which is typically examined in a Rule 15 analysis. See May 27, 2015 Order at 8 n.5.

the '096 and '148 Patents. Due to the relatedness of the three patents, Shire argues "the validity or infringement analysis ... would require looking at similar data, references, and testimony related to drug formulation, release and absorption, and treatment of ADHD." July 9, 2015 Letter Brief ("LB") at 4. Shire also argues that the relatedness of the three patents is evidenced by its assertion of the '768 Patent in other patent cases involving generic versions of Adderall XR® and by Amerigen's discovery requests for information related to the '768 patent in this case.

In contrast to Shire, Amerigen argues that the '768 Patent is unrelated because it is not within the '096 or '148 family trees and because it does not share any common patent application with the patents-in-suit. Amerigen also asserts that the patents are not related because the '768 Patent is not listed in the FDA's *Orange Book* in connection with Adderall XR®. In contrast, Amerigen points out that the '046 and '148 Patents-in-suit originated from the same parent application and both patents are listed in the *Orange Book* in connection with Adderall XR®. Additionally, Amerigen argues that while the three noted inventors of the '768 Patent are also listed inventors on the '046 and '148 Patents, the patents list five additional inventors. Amerigen also distinguishes several of Shire's specific assertions that the claims and specification of the three patents are the same or similar. Amerigen argues that because of the "marked" differences

between the patents-in-suit and the '768 Patent, different discovery will be needed which will be "highly disruptive" to the case. June 26, 2015 LB at 4. Amerigen contests that Shire's assertion of the '768 Patent in previous Adderall XR® cases is material to the relatedness issue and points out that it only propounded discovery related to the '768 Patent in response to Shire's threat of asserting the '768 Patent.

Discussion

Based on the record before the Court, the Court finds that the '768 Patent is sufficiently related to the patents-in-suit so that the '768 Patent could be added to the case under Rule 15. Thus, the effect of the Court's ruling is that Shire may review Amerigen's ANDA to determine if the '768 Patent is infringed even though the '768 Patent is not currently named in the complaint.

The Court starts its analysis by emphasizing that its "relatedness" analysis focuses on how the term is used in the context of Rule 15, not in a strict "patentese" sense. Thus, Amerigen's primary argument is not dispositive. See June 26, 2015 LB at 1. ("In other words, the '768 Patent is not a parent, continuation or divisional of either of the patents-in-suit, nor does it have any other relationship to those patents from the perspective of the U.S. Patent and Trademark Office.")

As discussed, even though the '798 Patent is not strictly related to the '046 and '148 Patents as that term is technically

used, it is still sufficiently related so as to permit joinder under Rule 15. The Court recognizes that the *Orange Book* does not list the '768 Patent for Adderall XR® and that the '768 Patent does not have any patent applications in common with the patents-in-suit. The Court also recognizes that the '768 patent has no familial relationship with the patents-in-suit. These facts, however, are not dispositive on the issue before the Court. In order to add a patent to an existing complaint courts do not require that patents be within the same family tree or part of the same patent application. Put another way, relatedness in the current context is not the equivalent of what it means to be literally related within a patent family tree. This is evidenced by the fact that some courts only require that a new patent be "potentially related" or relate "in some way" to the patents-in-suit in order to be joined to a case. See Masimo Corp. v. Philips Electronics N. Am. Corp., C.A. No. 09-80, 2010 WL 1609899, at \*1 (D. Del. Apr. 20, 2010); Aten Intern. Co., Ltd v. Emine Technology Co., Ltd., C.A. No. 09-0843, 2010 WL 1462110, \*3-\*5 (C.D. Cal. 2010).

The Court finds that the '046, '148 and '768 Patents are sufficiently related because, inter alia, the '768 Patent refers extensively to Adderall XR® and all three patents relate to components of pharmaceutical formulations suitable for oral

administration and delivery of amphetamine salts.<sup>3</sup> LG Electronics U.S.A., Inc. v. Whirlpool Corp., C.A. No. 10-311, 2011 WL 4043394, at \*2 (D. Del. 2011) (permitting amendment where all the patents concerned refrigerator technology). Additionally, the '768 Patent shares the same inventors involved in the patents-in-suit. See Aten, 2010 WL 1462110, at \*4 (finding new patents were sufficiently related when all the patents at issue related to the same technology and had the same inventor). While Amerigen's specific distinctions between the patents-in-suit and the '768 Patent are noted (see Amerigen LB 2-3), these arguments do not suggest that the patents are comprehensively unrelated. See Masimo, 2010 WL 1609899, at \*1. In fact, Amerigen does not argue and the Court does not find that the technology at issue is "totally different." Matsushita Elec. Indus. Co., 2007 WL 127997, at \*3. Rather, the Court finds that all three patents concern the same general technology and claim pharmaceutical formulations suitable for oral administration and delivery of amphetamine salts.

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<sup>3</sup>Shire writes, "[h]ere, all three patents claim Pharmaceutical formulations suitable for oral administration and delivery of Amphetamine Salts.... [A]ll three patents also recite limitations directed to release of amphetamine salts and the target amphetamine blood levels produced by the claimed formulations[.]" July 9, 2015 LB at 4. Shire also writes, "[v]arious claims of the '148 and '768 Patents are also directed towards the treatment of ADHD with amphetamine salts, dose proportionally, and the use of certain excipients." Id.

Even if the Court accepted Amerigen's argument that "simply referencing ADHD, a very common disorder, cannot be sufficient to demonstrate relatedness," Shire has demonstrated much more. Amerigen LB at 4. Shire has demonstrated that the '768 Patent makes similar, though not identical claims to the '046 and '148 Patents. For example, the Abstract of the '768 Patent notices "[a] pharmaceutical composition compris[ing] a once-a-day sustained release formulation of at least one amphetamine salt which provides mean plasma concentration profile aspects in human ADHD patients which are substantially the same as that provided by Adderall XR® type pulsatile formulations." Amerigen argues this overlap is "the equivalent of arguing that a tire patent and a headlight patent must be related merely because both can be associated with a car." Amerigen LB at 2. The Court disagrees. Although there is variation among the precise elements recited in the patents' claims, the analogy to tires and headlights is not appropriate. Rather, the Court agrees with Shire that a more appropriate analogy is three patents directed to methods of producing a particular kind of headlight. Shire Reply at 2.

The parties agree, and the Court has not found, a case on point and that the issue before the Court appears to be one of first impression. However, the line of cases the Court looks to for guidance, those addressing when new patent claims may be added

to existing litigation under Rule 15, support Shire.<sup>4</sup> In LG Electronics U.S.A., 2011 WL 4043394, at \*2, Whirlpool opposed LG's motion to add new patents to the case because the new claims would "unnecessarily complicate the litigation." The court permitted the amendment finding that all of the patents at issue concerned refrigerator technology. Id. In particular, the court noted that one new patent "while not directly comparable to the other patents-in-suit, was sufficiently related to the overall theme of refrigerator technology so as not to warrant a separate lawsuit."

Id.

Similarly, in Masimo Corp., 2010 WL 1609899, at \*1, Masimo opposed Philips' motion to assert a new counterclaim because the new patent was "unrelated to the patents already asserted in th[e] case." Masimo also argued that courts reject motions to add new claims which are not "closely related to the subject matter of the

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<sup>4</sup> Cases in this district provide limited guidance. In Osteotech, Inc. v. Regeneration Technologies, Inc., C.A. No. 06-4249 (FLW), 2008 WL 2036795 (D.N.J. May 9, 2008), the defendant argued that the addition of the plaintiff's proposed new patent claim would improperly expand the scope of the case. The plaintiff, conversely, contended the two patents concerned "exactly the same process." Id. at \*1. Without much discussion the court permitted the amendment and noted the plaintiff's representation that the two patents concerned "exactly the same process." Id. at \*2. In Astrazeneca AB v. Ranbaxy Pharm., Inc., C.A. No. 05-5553 (JAP), 2008 WL 5272018 (D.N.J. Dec. 16, 2008), the defendant argued it would be prejudiced by the addition of the plaintiff's proposed new patent claim. Id. at \*3. The court found that no undue prejudice would result and noted that the proposed new patent claim involved the "same product at issue" and would not "overly complicate [the] matter." Id.

original claims." Id. (citing Dluhos v. Strasberg, C.A. 00-3163 (JCL), 2005 WL 1683696, at \*2 n.3 (D.N.J. 2005)).<sup>5</sup> Philips, in opposition, argued that the new patent was "closely related to Philips' already-asserted patents and involves technology and products already at issue." Id. at \*2. Masimo attempted to distinguish the claims of the new patent and the patents-in-suit. Id. at \*2. The court rejected Masimo's arguments and permitted Philip's new counterclaim finding that it was appropriate to add the new patent which was "potentially related" to the technology at issue.

In Aten Intern. Co., supra, Aten sought to add three patents to a case which all related generally to KVM switches and shared a common inventor. Emine opposed Aten's motion, arguing that the new patents would introduce separate and distinct causes of action. 2010 WL 1462110, at \*3. The court permitted the amendment, noting that although only one of three proposed patents was within the same patent family, all three patents related "in some way" to KVM switches. Id. at \*4.

The decision in Matsushita Elec. Indus. Co. v. CMC Magnetics Corp., C.A. No. 06-04538, 2007 WL 127997, at \*3 (N.D. Cal. Jan. 12, 2007), contrasts with the foregoing authorities. In that case

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<sup>5</sup> The Masimo court distinguished the Dluhos case because in Dluhos the court found that undue delay would result if the pro se plaintiff was permitted to add claims which were "factually and analytically distinct" from the claims in the original complaint.

Matsushita opposed CMC's proposed counterclaim because it "dealt with totally different technology." Matsushita's complaint accused CMC's optical discs of infringing its patents, while CMC's proposed counterclaim accused Matsushita's DVD players of infringing its patents. Id. The court agreed with Matsushita and found that, "[t]he proposed counterclaim involves an entirely different product than Matsushita's infringement claims." Id. Stated a different way, the court found that the two technologies related "only in a very broad sense" and noted that the addition of the counterclaim would add undue complexity into the case, requiring jurors to learn the technology related to both optical storage media and DVD players. Id. at \*4. The situation in Matsushita is markedly different than what exists here.

As to Amerigen's argument that adding the '768 Patent will be "highly disruptive" to the case (Amerigen LB at 4), the argument is premature. Shire has not yet moved to add the '768 Patent. The issue will be addressed when and if Shire moves to amend its complaint to add the '768 Patent.

While the Court understands Amerigen's concern about its confidential information, the Court reiterates that to the extent Amerigen argues it is materially prejudiced by the Court's ruling or that its confidential information is being misused, the argument is overblown. The DCO makes it clear that Shire can only use Amerigen's confidential information in connection with this case.

The DCO also makes it clear that Shire cannot use Amerigen's confidential information for anti-competitive purposes. The Court and parties recognize that the DCO "is intended to prohibit parties from using confidential information to litigate separate actions and unrelated claims." Order at 12. Further, one must keep in mind that Shire already has a copy of Amerigen's ANDA. If Shire intended to misuse Amerigen's confidential information this already could have been done. The parties undoubtedly recognize that unless they mutually protect each other's confidential information and follow the strictures of the DCO, their patent claims and defenses cannot be effectively heard and decided. The parties have a joint interest in this occurring.

The Court again emphasizes that it is not deciding whether it will grant a motion to amend to add the '768 Patent to the case if the motion is filed. That issue is not before the Court. As repeatedly emphasized, the Court analyzes different factors in the present context than it will analyze to decide if Shire's motion to amend will be granted.

#### Conclusion

For the foregoing reasons, the Court finds that Shire has demonstrated that the '768 Patent is sufficiently related to the patents-in-suit so that an amendment would be permitted under Rule

15. Accordingly, Shire may review Amerigen's ANDA to determine if the '768 Patent was infringed.<sup>6</sup>

**ORDER**

Accordingly, for all the foregoing reasons,

IT IS on this 24th day of July, 2015 hereby

ORDERED that the parties' Discovery Confidentiality Order does not bar Shire from reviewing Amerigen's confidential information, including its ANDA, to determine if the '768 Patent was infringed.

s/ Joel Schneider  
JOEL SCHNEIDER  
United States Magistrate Judge

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<sup>6</sup> The fact that Amerigen may have requested discovery regarding the '768 Patent or that Shire filed different lawsuits where the '768 Patent was combined with other patents, is not material to the Court's decision.